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### **REMARKS**

Applicant would like to thank Examiner Prebilic and Examiner Pellegrino for a personal interview with Applicant's representative, Mr. John Sopko, on November 7, 2002.

The abstract has been amended in accordance with the specification in page 7, line 11.

The claims have been amended to place the application in condition for allowance, as discussed with the Examiner during the interview of November 22, 2002. In particular, amended independent claims 1, 11, 17 and 18 are directed to a radiation resistant and hydrolytically stable biocompatible fabric is stable at a temperature of at least about 120°C. None of these amendments constitute new matter. In view of the above amendments and remarks set forth herein, reconsideration is respectfully requested.

The Examiner has maintained the rejection of claims 1-3, 5, 6, 8 and 11-13 under 35 U.S.C. §102(b) as being anticipated by Kudo et al. (U.S. Patent No. 4,331,697). The Examiner maintains that Kudo allegedly discloses the invention as set forth in claims 1-3, 5, 6, 8 and 11-13 even though a fabric is not disclosed and certain physical properties, i.e., radiation resistance and hydrolytically stability, are not disclosed. In view of the amended claims 1 and 11, the rejection is respectfully traversed.

Claims 1 and 11 have been amended to include a fabric stable at a temperature of at least about 120°C. Kudo fails to disclose a fabric stable at least about 120°C as in amended claims 1 and 11.

Further, the Examiner has rejected claim 18 under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, under 35 U.S.C. §103(a) as being obvious over Kudo. The Examiner acknowledges Kudo does not explicitly recite how the entire process of obtaining the product is

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performed. The Examiner alleges Kudo discloses shaping the polymer which is allegedly the same as the device described in the specification. The Examiner alleges it can be assumed the Kudo device will inherently perform the claimed process.

Kudo fails to teach, suggest or disclose a process of forming a fabric stable at a temperature of at least 120°C of amended claim 18. Kudo teaches away from amended claim 18. Kudo discloses temperatures higher than 100°C are undesirable because the elevated temperature deactivates the heparin. The rejection is traversed.

The Examiner has additionally maintained a rejection of claims 4, 9, 10 and 14-17 under 35 U.S.C. §103(a) as being unpatentable over Kudo et al. in view of Schmitt (U.S. Patent No. 5,443,499). The Examiner alleges Kudo satisfies the claim language except Kudo fails to disclose the construction of the polymer or the number of filaments used and the diameter of the material with a stent. The Examiner alleges Schmitt satisfied Kudo's deficiencies and it would be obvious to combine Kudo and Schmitt.

Amended claims 1, 11 and 17 are directed to a radiation resistant and hydrolytically stable biocompatible fabric stable at a temperature of at least about 120°C. Kudo individually or in combination with Schmitt fails to teach, suggest or disclose a fabric stable at a temperature of at least about 120°C. Kudo teaches away from amended claim 1, 11, and 17. Kudo discloses temperatures higher than 100°C are undesirable because the elevated temperature deactivates the heparin, col.5 line15-17. Further, Kudo fails to teach, suggest or disclose the use of naphthalene dicarboxylate derivative as a fabric or a textile. Kudo discloses use of the polymer in a non-textile or non-fabric manner, such as extruding, molding, coating or laminating. See col. 8 line 67 continued to col. 9 line 9, and Examples 6, 7, 14 -19. Furthermore, Kudo requires its polymer to be chemically modified for subsequent heparin bonding, col. 7 lines 7-10, and line 51-55.

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Thus, Kudo not only fails to teach or suggest the present invention, but Kudo also teaches away from the present invention. Moreover, modification of Kudo to provide a fabric which is hydrolytically stable at 120°C would destroy the function of Kudo. The Examiner alleges Schmitt is directed to a braided tubular prosthesis that has 115 denier and 100 filaments which could be implanted along with a stent. Schmitt, however fails to remedy the deficiencies of Kudo. Thus, Kudo and Schmitt, individually or in combination, fails to teach or suggest the present invention. Reconsideration and withdrawal of the claims rejection are respectfully requested.

Furthermore, the Examiner has maintained a rejection of claims 4 and 14-16 under 35 U.S.C. §103(a) as being unpatentable over Kudo in view of Barone et al. (European Patent No. 461791). The Examiner alleges Kudo discloses all the elements of claim 4, and 14-16 except the graft construction of use with a stent. The Examiner alleges Barone teaches graft maintenance for use in vascular bodies can be woven construction and the graft material is to be used with a support structure in the form of a stent. The Examiner alleges it would be obvious to combine the construction and application of graft material with a support structure as taught by Barone for the graft of Kudo in order to effectively repair a collapsed blood vessel by using the combination stent-graft. Barone fails to cure the above-discussed deficiencies of Kudo. Barone fails to teach or suggest a radiation resistant and hydrolytically stable compatible fabric stable at a temperature of at least about 120°C. Thus Kudo and Barone, individually or in combination, fail to teach or suggest the present invention. Reconsideration and withdrawal of the claim rejections are respectfully requested.

In view of the above amendments and remarks, as noted by the above Examiner in the interview summary remarks, the invention would be defined over Kudo by amending the claims 1, 11, 17 and 18 to recite that a certain temperature, i.e., 120°C, the fabric is stable. Accordingly, Applicants believe the claims to be in condition for allowance. As such, entry of this

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amendment, withdrawal of the rejections and favorable action are respectfully solicited. Should the Examiner have any questions regarding this response or wish to discuss any of these matters in further detail, please do not hesitate to contact Applicants' undersigned attorney.

Respectfully submitted,



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**VERSION OF AMENDMENT WITH MARKINGS**

**SHOWING CHANGES MADE**

**IN THE CLAIMS:**

1. (Amended) An implantable prosthesis having improved mechanical and chemical properties comprising:
  - a radiation resistant and hydrolytically stable biocompatible fabric having inner and outer surfaces and first and second ends;
  - said fabric having a textile construction of a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative, wherein said radiation resistant and hydrolytically stable biocompatible fabric is stable at a temperature of at least about 120°C.
11. (Amended) An implantable prosthesis having improved mechanical and chemical properties comprising:
  - a radiation resistant and hydrolytically stable biocompatible tubular fabric of a textile construction,
  - said fabric having a plurality of yarns selected from the group consisting of polyethylene naphthalate, polybutylene naphthalate and combinations thereof, wherein said radiation resistant and hydrolytically stable biocompatible fabric is stable at a temperature of at least about 120°C.
17. (Amended) Method for making a radiation and thermal resistant and hydrolytically stable, steam sterilizable biocompatible prosthesis comprising:
  - a) providing a fabric having an inner and outer surface and first and second ends, said fabric having a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative, wherein said fabric being stable at a temperature of at least about 120°C;

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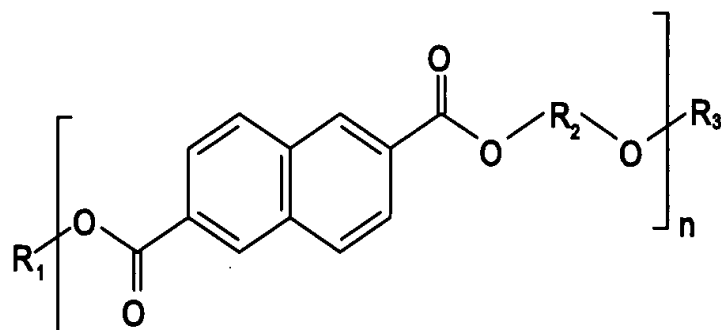
- b) selecting a textile construction pattern; and
- c) forming said prosthesis in accordance with a textile construction pattern.

18. (Amended) Implantable prosthesis comprising a fabric having improved chemical and mechanical properties formed by the process comprising:

- a) providing a fabric having an inner and outer surface and first and second ends, said fabric having a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative, said fabric being stable at a temperature of at least about 120°C;
- b) selecting a textile construction
- c) forming said prosthesis in accordance with a textile pattern; and
- d) steam sterilizing said prosthesis.

### IN THE ABSTRACT:

Prostheses with improved chemical and mechanical properties manufactured that includes a radiation resistant and hydrolytically stable biocompatible fabric having outer and first and second ends with a textile fabric that includes a naphthalene dicarboxylate derivative polymer having the general formula:



wherein R<sub>1</sub> and R<sub>3</sub> are the same or different groups and are independently selected from the naphthalene dicarboxylate derivative repeating unit (I), a hydrogen radical and a methyl radical. R<sub>2</sub> is an ~~alkyl~~ alkylene radical having 1 to 6 carbon atoms; n is from 10 to 200. Also contemplated are implantable prostheses that are flat constructions useful as patches and filters or tubular constructions useful as vascular grafts. A further aspect of this invention provides a method for making a radiation and thermal resistant and hydrolytically stable, steam sterilizable biocompatible prosthesis.